

wherein said plasmid comprises a DNA molecule that encodes at least one BS322 epitope and is selected from the group consisting of: SEQ ID NOS:24-28 and degenerate codon equivalents thereof.

### **REMARKS**

Applicant confirms the provisional election made to prosecute the invention of Group II (claims 23-25, 28-29, 36-37, 39-40 and 51). Claims 1-51 have been canceled and new claims 52-81 have been added.

The specification is objected to because the sequence identifiers do not conform to the Sequence Rules. Applicant apologizes. In light of the above amendments, Applicant respectfully submits that the informalities in the specification have been corrected and requests that this objection be withdrawn.

Claims 23-25, 28-29, 36-37, 39-40 and 51 are objected to because the sequence identifiers do not conform to the Sequence Rules. Applicant apologizes. These claims have been canceled and the new claims conform to the Sequence Rules. Applicant respectfully submits that the new claims are in a condition for allowance and requests that this objection be withdrawn.

Claims 23-25, 28-29, 36-37, 39-40 and 51 are rejected under 35 USC 101 because the claimed invention is not supported by either a specific, substantial or credible asserted utility or a well-established utility. The Examiner states that the use of non-breast libraries as a control to breast tissue libraries is inappropriate since the specification as filed does not indicate that the non-breast libraries were derived from "normal" tissues, i.e. non-diseased tissues." Applicant vigorously disagrees that this is so.

As is known by scientists skilled in diagnostic arts using gene markers, a gene product, such as a protein or messenger RNA (mRNA) coding for the protein, which is more prevalent and specific to one tissue type (the host tissue) than other tissue types, is extremely useful as a marker for the detection of disease in the host tissue. If a protein appears in a tissue or body component where the normal occurrence of the protein is very low or non-existent, then the specific tissue in which the protein is normally found is in a

diseased state. This is because the disease causes an alteration to the protein-specific tissue which results in the protein escaping from its normal tissue to another tissue or another component of the body. There are three main conditions which cause a tissue-specific protein to exist outside its specific (normal) host tissue: massive trauma, ischemia and hypertrophic proliferation. Thus, if a patient has not experience a massive trauma or ischemia, detection of a tissue-specific protein outside the specific (normal) host tissue of the protein indicates that the condition causing the presence of the protein outside its normal host tissue is hypertrophic proliferation of the host tissue. The most serious form of hypertrophic proliferation is cancer.

Therefore, Applicant asserts that the examples and methods disclosed in the specification are enabling for, at the least, breast diseases that may be detected using gene markers and related gene marker technology. Nevertheless, in an effort to clarify, Applicant submits new claims 52-81 which include the terms "breast cancer" and "breast hypertrophic proliferation" in addition to "breast disease". Applicant respectfully submits that the new claims are now in a condition for allowance and requests that this rejection be withdrawn.

Claims 23-25, 28-29, 36-37, 39-40 and 51 are rejected under 35 USC 112, first paragraph. The Examiner states that there is no evidence that it is only required that a protein maintains 50% identity to the claimed polypeptide sequence therefore the genus of polypeptides is highly variant and neither the specification or claims provide guidance as to what specific changes should be made. These claims have been canceled.

However, as stated above, some of new claims 52-81 recite "identity" language. Applicant asserts that identity language is one means of providing guidance as to the variety of species that may be reasonably discerned from the specification and/or sequence data in the specification by persons skilled in the art. Nevertheless, in an effort to expedite prosecution, Applicant respectfully submits new claims 52-81, which raise the percent identity and include language to clarify that identity is "over the entire length" of the claimed SEQ ID NO. Applicant respectfully submits that the new claims are in a condition for allowance and requests that this rejection be withdrawn.

Furthermore, new claims 52-81 include language to clarify that the polynucleotides of the present invention are “purified” and/or “isolated.”

New claims 52-81 are further clarified by “degenerate codon equivalents” language. The degeneracy of the genetic code is a concept that is well-known to those skilled in the art and is even discussed in section 2144.09 of the February 2000 revision of the Manual for Patent Examining Procedure as “the fact that most amino acids are specified by more than one nucleotide sequence or codon.” Applicant respectfully submits that the new claims are in a condition for allowance and requests that this rejection be withdrawn.

Claims 23-25, 28-29, 36-37, 39-40 and 51 are rejected under 35 USC 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention. In view of the above remarks, Applicant respectfully submits that the new claims are in a condition for allowance and requests that this rejection be withdrawn.

Claims 23-25, 28-29, 36-37, 39-40 and 51 are rejected under 35 USC 112, second paragraph as being indefinite.

The Examiner states that there is ambiguity in claims 23, 26, 28, 36, 39-40 and those dependent therefrom, which recite “and fragments thereof”. Applicant respectfully disagrees. The term “fragment” is clearly defined at page 13, line 28 to page 14, line 5 of the specification. However, in an effort to expedite prosecution, claims 23, 26, 28, 36, 39-40 have been canceled and new claims 52-81 do not include “fragment” language. New claims 10-15 are further clarified by “degenerate codon equivalents” language as discussed above. Applicant respectfully submits that the new claims are in a condition for allowance and requests that this rejection be withdrawn.

The Examiner states that there is lack of antecedent basis for the limitation “the presence” in claims 28 and 36. These claims have been canceled. New claims 52-81 have been appropriately amended. Applicant respectfully submits that the new claims are in a condition for allowance and requests that this rejection be withdrawn.

**CONCLUSION**

In view of the aforementioned amendments and remarks, Applicant respectfully submits that the above-referenced application is now in a condition for allowance and Applicant respectfully requests that the Examiner withdraw all outstanding objections and rejections and passes the application to allowance.

Respectfully submitted,  
P.A. Billing-Medel, *et al.*

A handwritten signature in cursive script, reading "Cheryl L. Becker", written in dark ink.

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